THE NEED FOR SMARTER INVENTORY TRACKING

Larry Hall, Tracelink, discusses how serialization is driving demand for smarter inventory tracking and warehouse management

By Pharma Logistics Editor

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Enforcement of DSCSA and FMD have created demand for smarter inventory tracking and more efficient warehousing operations to meet both regulatory and efficiency demands.

Warehouse management systems are highly complex, heavily customized and most can't handle serialization requirements or deliver the reporting capabilities necessary to accommodate mandates.

The following use cases highlight the growing complexity of the challenges that warehouse operations must consider to deliver compliant processes.

Product leaving the supply chain prior to point of dispense and serial number status changes for FMD

Articles 16, 22 and 23 of the FMD regulation affect companies responsible for pharmaceutical distribution in the EU and require decommissioning and reporting of serial numbers for products that have left the supply without being dispensed.

This includes:

- Article 16: Decommission before repackaging or relabeling for free samples or clinical trial product.
- Article 22: Decommission for product exported from the EU, unsaleable product, and product to be destroyed.
- Article 23: Decommission for product distributed to non-healthcare institutions such as schools or nursing homes that aren't required by law to decommission medicines.

Adherence to each article requires reporting to either the European Medicines Verification System (EMVS) or the appropriate National Medicines Verification System (NMVS).

As each of these articles results in exceptions to normal warehouse operations, there is an impact on workflow and with that, comes a number of inherent complexities to be managed. Most prominently, operational teams must figure out which system, the NMVS or the EMVS must be notified for each product and then spend time on the actual decommission reporting. These additional processes could distract from core activities where resources can be used more efficiently, such as managing inventory or receiving, packing, and shipping within the warehouse.

There are also requirements around serial number status changes. The normal path of distribution is defined as product moving from the manufacturer to wholesaler/3PL and then pharmacy or point of dispense where the product is decommissioned from the supply chain. If, when travelling along this path, a product has been damaged or locked for investigation, its serial number status must be changed in the respective NMVS. This can also occur if a product was incorrectly reported to the NMVS, in which case an organisation will have ten business days to make the correction to the appropriate government system.

Returned Product for DSCSA and FMD

Both the FMD and DSCSA require warehouse operators to verify returned product intended to be put back in stock for redistribution. Warehouses have previously relied on manual, paper-based processes and phone calls for verification when asked to confirm and decommission a product that came from their site.

If a wholesale distributor introduces product into their facilities that was not purchased directly from the Marketing Authorization Holder (MAH) or a designated wholesaler, then the product must be verified, per FMD. This risk-based verification requires 100 percent of returned product to be verified before it can be put back into the market for resale. Bringing risk-based verification into processes to ensure compliance is going to create the need for operational warehouse changes including staffing and standardizing processes. Without an automated solution in place to verify product, the process can become lengthy and costly.

The DSCSA track and trace law offers a more direct mandate with a November 2019deadline. This U.S. saleable returns verification requirement mandates that wholesalers verify the serialized product identifiers for any saleable products that have been returned, before they can be restocked and resold. Wholesalers and manufacturers will need to work together to ensure wholesalers have access to information from the manufacturer in a timely manner. It is critical that this new requirement does not slow down the receiving and return receipt process for wholesalers. Whether companies approach this requirement with self-verification or a Verification Router Service (VRS), selecting a solution that minimises the impact saleable returns has on workflow disruptions will be crucial to compliance and operational success.

Managing Complexities in the Warehouse for both DSCSA and FMD

With all of these complex requirements, staying compliant, while also running efficient warehouse operations can seem challenging. However, with a cloud-based network approach, automated verification can be done in real-time, freeing warehouse staff from the complex and error-prone manual verification processes and allowing them to focus on core operational tasks.

An application that can layer serialization requirements alongside a warehouse management system, rather than embed them into one, would allow for real-time information scanning. When product is scanned, data capture is automated and this greatly reduces or eliminates the potential of errors, for example, capturing the wrong serial number. Additionally, a solution that can run on any mobile device will streamline processes and increase business efficiencies.

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